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DICKSTEIN SHAPIRO LLP
1825 EYE STREET NW
Washington, DC 20006-5403

EXAMINER	
EREZO, DARWIN P	

ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,239	SCHUBERT, HEINRICH	
	Examiner	Art Unit	
	Darwin P. Erezo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,30 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 5/22/09.

Claim Objections

2. Claim 1 is objected to because of the following informalities:

3. In line 10, the applicant uses the term "operable". However, in viewing the limitations of independent claims 19, 29 and 30, it appears that the claim limitation should read --openable-- instead of "operable"

4. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-4, 7-9, 11, 14, 15, 18, 19, 21, 23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,774,615 to Lim et al., in view of US 4,873,975 to Walsh et al., US 5,188,638 to Tzakis and US 3,357,432 to Sparks.

In Fig. 3, Lim discloses the use of anastomosis connector comprising an inner sleeve **1** mounted on an end of a first hollow organ **2** such that the end can be everted over the inner sleeve; and an outer sleeve **4** mounted around the end of a second hollow organ **3**; wherein an outer circumference of the entire end portion of the inner sleeve over which the first organ lies is smooth (see Fig. 3).

Lim discloses that the inner and outer sleeve can be made of inert materials, though a preference is provided for outer sleeve to be made of metal and the inner sleeve to be made of hydrophilic material. Thus, Lim fails to teach both the inner and outer sleeves comprising electrically conductive materials. However, the use of metallic material to form both inner and outer sleeves are well known in the art. For instance, Walsh discloses an anastomotic connector comprising an inner and outer sleeves that are made of electrically conductive materials, such as stainless steel (col. 12, ll. 34-44), thus being electrically conductive. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inner sleeve of Lim to be made of an electrically conductive material since the use of said material is well known in the art, as taught by Walsh, and that it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197,

125 USPQ 416 (CCPA 1960). Note that a metal is an inert material and would not destroy the teachings of Lim.

The modified device of Lim would have both the inner and outer sleeve be made of electrically conductive material; wherein at least one contact surface made of electrically conductive material is disposed at least one of the outer surface of the inner sleeve and the inner surface of the outer sleeve; wherein the contact surfaces on the inner sleeve and the outer sleeve are arranged circumferentially (arrangement shown in Fig. 3); wherein any portion of the inner and outer sleeve can be viewed as a predefined breaking sites (an area that can be cut); wherein outer sleeve can be formed by a wire arranged in the shape of a loop (Fig. 2); wherein the outer sleeve has a protrusion and the inner sleeve has a channel for receiving said protrusion, as seen in Fig. 3, wherein the protrusion/channel are fitting elements; wherein a control means can be connected to the current source (note that the external current is not positively recited in the claims); wherein the sleeves are substantially cylindrical; wherein the inner circumference of the outer sleeve that contacts that tissue is smooth.

The modified device of Lim is silent with regards to the inner and outer sleeve being separable or openable that permits the removal of the sleeves without severing the first and second hollow organs. However, the use of separable or openable outer and inner sleeves are well known in the art. For example Tzakis discloses an inner sleeve in Fig. 1 that is formed with two halves. Sparks discloses an outer sleeve in Fig. 4 that is openable. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to also have the inner and outer sleeve of Lim to

be separable or openable as it would allow for the device to be removed from the tissues. It would also make it easier to install the device into and over the tissue.

8. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. in view of Walsh et al., as applied to the rejection to claim 1 above, and in further view of US 3,435,823 to Edwards.

The modified device of Lim discloses all the limitations of the claims except for the outer sleeve being constructed of pivotable components having catch elements. However, the use of a pivotable outer sleeve is well known in the art. Edwards discloses an anastomosis connector having an outer sleeve **60**, wherein the outer sleeve is pivotable with catch elements. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lim to have an outer sleeve that is pivotable as it would make it easier for a practitioner to secure the outer sleeve on the anastomosis site.

9. Claims 12, 13, 16, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. in view of Walsh et al., as applied to the rejection to claim 1 above, and in further view of US 5,649,937 to Bito et al.

The modified device of Lim discloses all the limitations of the claim except for the device having a sensor for measuring the impedance or temperature of the device, or wherein the device is connected to a current source. However, the use of current to enhance an anastomotic site is well known in the art, as disclosed by Bito. Bito discloses an anastomotic device having sensors **26** for providing various parameters for the device, and wherein a current is provided to anastomotic connector for

electrocoagulation of the tissues. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use modify the device of Lim to include sensors and be connected to an electric current because providing an electric current to an anastomotic connector will enhance the integrity of the seal between the first and second hollow organs via electrocoagulation.

10. Claims 10, 24, 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. in view of Walsh et al., as applied to the rejection to claim 1 above, and in further view of US 5,861,168 to Cooke et al.

The modified device of Lim discloses all the limitations of the claim except for portions of the inner and outer sleeves to be formed of a plastic material. However, forming vascular support devices from a combination of metal and plastic is well known in the art. For example, Cooke discloses a stent structure formed from metals, ceramics, plastics or combinations there of (col. 6, ll. 49-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lim to be made of a combination of metal and plastic since such combination is well known in the art, as taught by Cooke, and that it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Furthermore, the applicant does not provide any criticality to the inner and outer sleeves being formed of a combination of materials since the applicant also discloses an embodiment wherein the inner and outer

sleeves are made of only metal. Thus, having a combination of metal and plastic would also be a mere obvious design choice to one of ordinary skill in the art.

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

It is also noted that the applicant argued that Lim fails to disclose a device capable of production of an electrocoagulated anastomosis. However, the Lim reference is being modified with the teachings of Walsh to provide a device that is fully made of metal, which is capable of production of an electrocoagulated anastomosis. Note that Lim already teaches one of the sleeves to be made of a metal material. The teachings of Walsh is merely provided to show that it is known in the art to have both components of an anastomotic connector to be made of metal. Having both components made of metal would also provide a stronger, more resilient anastomosis connector. The modification to the Lim reference to have both components made of metal would also make the device of Lim fully capable of production of an electrocoagulated anastomosis.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773